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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,926	07/29/2005	Walter H. Hsu	08411-041US1	4316

26191 7590 07/03/2006

FISH & RICHARDSON P.C.
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/509,926	Applicant(s) HSU ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Preliminary Amendment.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1Oct2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4-20-05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants' Preliminary Amendment is acknowledged.
2. Claims 1-33 are pending and under consideration.

Priority

3. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

The specification does not contain a priority statement in the first sentence.

Specification

4. The disclosure is objected to because of the following informalities:

Page 11, line 27, "i" should be "in".

Page 12, line 26, what is an "osyngeneic" mouse?

Page 14, line 21, "hyoneumoniae" should be "hyopneumoniae".

Appropriate correction is required.

Drawings

5. Figure 5 is objected to under 37 CFR 1.83(a) because it fails to show "Rc" as described in the specification, page 5, line 30. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action

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to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

6. Figure 11 is objected to under 37 CFR 1.83(a) because it fails to show "positive band at about 65kDa in Lanes 1 and 3" as described in the specification, page 7, line 5. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *M. hyopneumoniae* membrane proteins with molecular weights of about 30 to about 100 kDa which increase calcium release from porcine ciliated tracheal cells, does not reasonably provide enablement for the range of the instant claims, i.e., any/all polypeptides from any/all other sources with a molecular weight of about 30 to about 150 kDa. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention is substantially pure polypeptides which increase calcium release from porcine ciliated tracheal cells wherein said polypeptides are between about 30 kDa and about 150 kDa, and methods of use.

The state of the prior art concerning calcium release from porcine ciliated tracheal cells indicates that some bacteria and compounds do increase calcium release.

However, there is a lack of predictability in the art concerning the ability of any/all polypeptides from any/all sources to increase calcium release from porcine ciliated tracheal cells wherein said polypeptides are between about 30 kDa and about 150 kDa.

The amount of direction or guidance present in the specification indicates that five polypeptide bands corresponding to molecular weights 30, 60, 65, 90, and 120 kDa are present in outer membranes of pathogenic *M. hyopneumoniae* versus nonpathogenic *M.*

hyopneumoniae (page 23, lines 8-12) and that the ability of these polypeptides to cause the calcium release increase was between 30 and 100 kDa in size (page 24, lines 7-12). The specification does not teach any polypeptides with the claimed ability that are above 100-120 kDa in size, nor does the specification teach that any/all polypeptides from any/other sources, even from nonmembrane preparations of *M. hyopneumoniae* possess the required activity.

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Therefore, the broad scope of the instant claims constitute merely an invitation to experiment without a reasonable expectation of success.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Ross et al (WO95/09870).

Claims 1-13 are drawn to a polypeptide from *M. hyopneumoniae* with a molecular weight between about 30 kDa and about 150 kDa wherein said polypeptide increases calcium release from porcine ciliated tracheal cells.

Ross et al teach isolated polypeptides from *M. hyopneumoniae* with a molecular weight between about 43 kDa and about 150 kDa which are involved in attachment to ciliated cells (Abstract; page 8, lines 12-22). While Ross et al do not specifically test calcium release, in the absence of evidence to the contrary, the ability of the polypeptides of Ross et al to induce calcium release is an inherent capability of the polypeptides.

Claims 14-27 are drawn to antibodies which are capable of binding, a method of inducing said antibodies, and a method of binding, to the polypeptides of instant claims 1-13. Ross et al teach monoclonal antibodies which bind to polypeptides from *M. hyopneumoniae* with a molecular weight between about 43 kDa and about 150 kDa which are involved in attachment

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to ciliated cells (Abstract; page 8, lines 12-22; page 10, line 8 to page 11 line 15; Ex. I.4(pages 14-15); Ex. XVI).


Conclusion

11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

June 24, 2006